

MEDICATION GUIDE
SUBOXONE[®] (Sub-OX-own)
(buprenorphine and naloxone)
Sublingual Tablet (CIII)

IMPORTANT:

Keep SUBOXONE sublingual tablet in a secure place away from children. Accidental use by a child is a medical emergency and can result in death. If a child accidentally uses SUBOXONE sublingual tablet, get emergency help right away.

Read this Medication Guide that comes with SUBOXONE sublingual tablet before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor. Talk to your doctor or pharmacist if you have questions about SUBOXONE sublingual tablet.

Share the important information in this Medication Guide with members of your household.

What is the most important information I should know about SUBOXONE sublingual tablet?

- Buprenorphine is a medicine in SUBOXONE sublingual tablet that can cause serious and life-threatening problems, especially if you take or use certain other medicines or drugs. Call your healthcare provider right away or get emergency help if you:
 - feel faint or dizzy
 - have mental changes such as confusion
 - have slower breathing than you normally have
 - have severe sleepiness
 - have blurred vision
 - have problems with coordination
 - have slurred speech
 - cannot think well or clearly
 - have slowed reflexes
 - have a high body temperature
 - feel agitated
 - have stiff muscles
 - have trouble walking
- These can be signs of an overdose or other serious problems.
- Do not switch from SUBOXONE sublingual tablet to other medicines that contain buprenorphine without talking with your doctor. The amount of buprenorphine in a dose of SUBOXONE sublingual tablet is not the same as the amount of buprenorphine in other medicines that contain buprenorphine. Your doctor will prescribe a starting dose of SUBOXONE sublingual tablet that may be different than other buprenorphine containing medicines you may have been taking.
- SUBOXONE sublingual tablet contains an opioid that can cause physical dependence.
 - Do not stop taking SUBOXONE sublingual tablet without talking to your doctor. You could become sick with uncomfortable withdrawal signs and symptoms because your body has become used to this medicine.
 - Physical dependence is not the same as drug addiction.
 - SUBOXONE sublingual tablet is not for occasional or “as needed” use.
- An overdose and even death can happen if you take benzodiazepines, sedatives, tranquilizers, antidepressants, or alcohol while using SUBOXONE sublingual tablet. Ask your doctor what you should do if you are taking one of these.
- Call a doctor or get emergency help right away if you:
 - Feel sleepy and uncoordinated
 - Have blurred vision
 - Have slurred speech
 - Cannot think well or clearly
 - Have slowed reflexes and breathing
- Do not inject (“shoot-up”) or snort SUBOXONE sublingual tablet.
- Injecting SUBOXONE sublingual tablet may cause life-threatening infections and other serious health problems.

- Crushing and/or dissolving SUBOXONE sublingual tablet and then injecting it (“shooting up”) could cause serious precipitated withdrawal (sudden, serious, withdrawal symptoms such as pain, cramps, vomiting and diarrhea) in people who are physically dependent on other opioids.
- Snorting SUBOXONE sublingual tablet could cause precipitated withdrawal.
- In an emergency, have family members tell emergency department staff that you are physically dependent on an opioid and are being treated with SUBOXONE sublingual tablet.
- Never give anyone else your SUBOXONE sublingual tablet. They could die from taking it. Selling or giving away SUBUTEX is against the law.
- Store SUBOXONE sublingual tablet securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

What is SUBOXONE sublingual tablet?

- SUBOXONE sublingual tablet is a prescription medicine used to treat adults who are addicted to (dependent on) opioid drugs (either prescription or illegal) as part of a complete treatment program that also includes counseling and behavioral therapy.

SUBOXONE sublingual tablet is a controlled substance (CIII) because it contains buprenorphine, which can be a target for people who abuse prescription medicines or street drugs. Keep your SUBOXONE sublingual tablet in a safe place to protect it from theft. Never give your SUBOXONE sublingual tablet to anyone else; it can cause death or harm them. Selling or giving away this medicine is against the law.

- It is not known if SUBOXONE sublingual tablet is safe or effective in children.

Who should not take SUBOXONE sublingual tablet?

Do not take SUBOXONE sublingual tablet if you are allergic to buprenorphine or naloxone.

What should I tell my doctor before taking SUBOXONE sublingual tablet?

SUBOXONE sublingual tablet may not be right for you. Before taking SUBOXONE sublingual tablet, tell your doctor if you:

- Have liver or kidney problems
- Have trouble breathing or lung problems
- Have an enlarged prostate gland (men)
- Have a head injury or brain problem
- Have problems urinating
- Have a curve in your spine that affects your breathing
- Have gallbladder problems
- Have adrenal gland problems
- Have Addison’s disease
- Have low thyroid (hypothyroidism)
- Have a history of alcoholism
- Have mental problems such as hallucinations (seeing or hearing things that are not there)
- Have any other medical condition
- Are pregnant or plan to become pregnant. If you take SUBOXONE sublingual tablet while pregnant, your baby may have signs of opioid withdrawal at birth. Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy. Talk to your doctor if you are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed. SUBOXONE can pass into your milk and may harm your baby. Talk to your doctor about the best way to feed your baby if you take SUBOXONE sublingual tablet. Monitor your baby for increased sleepiness and breathing problems.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SUBOXONE sublingual tablet may affect the way other medicines work, and other medicines may affect how SUBOXONE sublingual tablet works. Some medicines may cause serious or life-threatening medical problems when taken with SUBOXONE sublingual tablet.

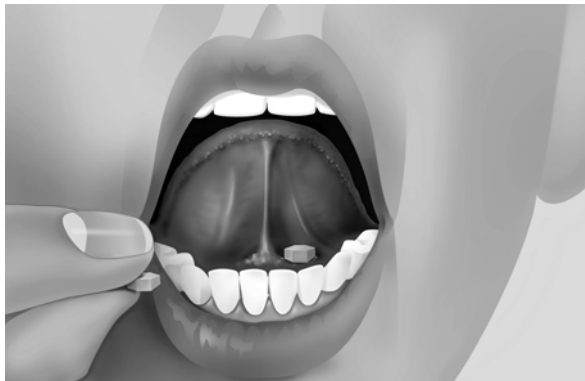
Sometimes the doses of certain medicines and SUBOXONE sublingual tablet may need to be changed if used together. Do not take any medicine while using SUBOXONE sublingual tablet until you have talked with your doctor. Your doctor will tell you if it is safe to take other medicines while you are taking SUBOXONE sublingual tablet.

Be especially careful about taking other medicines that may make you sleepy, such as muscle relaxants, pain medicines, tranquilizers, antidepressant medicines, sleeping pills, anxiety medicines or antihistamines.

Know the medicines you take. Keep a list of them to show your doctor or pharmacist each time you get a new medicine.

How should I take SUBOXONE sublingual tablet?

- Always take SUBOXONE sublingual tablet exactly as your doctor tells you. Your doctor may change your dose after seeing how it affects you. Do not change your dose unless your doctor tells you to change it.
- Do not take SUBOXONE sublingual tablet more often than prescribed by your doctor.
- If you are prescribed a dose of 2 or more SUBOXONE sublingual tablet tablets at the same time:
 - Ask your doctor for instructions on the right way to take SUBOXONE sublingual tablet
 - Follow the same instructions every time you take a dose of SUBOXONE sublingual tablet
- Put the tablets under your tongue. Let them dissolve completely.



- While SUBOXONE sublingual tablet is dissolving, do not chew or swallow the tablet because the medicine will not work as well.
- Talking while the tablet is dissolving can affect how well the medicine in SUBOXONE sublingual tablet is absorbed.
- If you miss a dose of SUBOXONE sublingual tablet, take your medicine when you remember. If it is almost time for your next dose, skip the missed dose and take the next dose at your regular time. Do not take 2 doses at the same time unless your doctor tells you to. If you are not sure about your dosing, call your doctor.
- Do not stop taking SUBOXONE sublingual tablet suddenly. You could become sick and have withdrawal symptoms because your body has become used to the medicine. Physical dependence is not the same as drug addiction. Your doctor can tell you more about the differences between physical dependence and drug addiction. To have fewer withdrawal symptoms, ask your doctor how to stop using SUBOXONE sublingual tablet the right way.
- **If you take too much SUBOXONE sublingual tablet or overdose, call Poison Control or get emergency medical help right away.**

What should I avoid while taking SUBOXONE sublingual tablet?

- **Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how this medication affects you.** Buprenorphine can cause drowsiness and slow reaction times. This may happen more often in the first few weeks of treatment when your dose is being changed, but can also happen if you drink alcohol or take other sedative drugs when you take SUBOXONE sublingual tablet.
- **You should not drink alcohol while using SUBOXONE sublingual tablet**, as this can lead to loss of consciousness or even death.

What are the possible side effects of SUBOXONE sublingual tablet?

SUBOXONE sublingual tablet can cause serious side effects, including:

- See “What is the most important information I should know about SUBOXONE sublingual tablet?”
- **Respiratory problems.** You have a higher risk of death and coma if you take **SUBOXONE sublingual tablet** with other medicines, such as benzodiazepines.
- **Sleepiness, dizziness, and problems with coordination**
- **Dependency or abuse**
- **Liver problems.** Call your doctor right away if you notice any of these signs of liver problems: Your skin or the white part of your eyes turning yellow (jaundice), urine turning dark, stools turning light in color, you have less of an appetite, or you have stomach (abdominal) pain or nausea. Your doctor should do tests before you start taking and while you take SUBOXONE sublingual tablet.
- **Allergic reaction.** You may have a rash, hives, swelling of the face, wheezing, or a loss of blood pressure and consciousness. Call a doctor or get emergency help right away.
- **Opioid withdrawal.** This can include: shaking, sweating more than normal, feeling hot or cold more than normal, runny nose, watery eyes, goose bumps, diarrhea, vomiting, and muscle aches. Tell your doctor if you develop any of these symptoms.
- **Decrease in blood pressure.** You may feel dizzy if you get up too fast from sitting or lying down.

Common side effects of SUBOXONE sublingual tablet include:

- Nausea
- Vomiting
- Drug withdrawal syndrome
- Headache
- Sweating
- Numb mouth
- Constipation
- Swollen and/or painful tongue
- The inside of your mouth is more red than normal
- Intoxication (feeling lightheaded or drunk)
- Disturbance in attention
- Irregular heart beat (palpitations)
- Decrease in sleep (insomnia)
- Blurred vision
- Back pain
- Fainting
- Dizziness
- Sleepiness

Tell your doctor about any side effect that bothers you or that does not go away.

These are not all the possible side effects of SUBOXONE sublingual tablet. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store SUBOXONE sublingual tablet?

- Store SUBOXONE sublingual tablet at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep SUBOXONE sublingual tablet in a safe place, out of the sight and reach of children.**

How should I dispose of unused SUBOXONE sublingual tablet?

- Dispose of unused SUBOXONE sublingual tablet as soon as you no longer need them.
- Dispose of expired, unwanted or unused SUBOXONE sublingual tablets by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

If you need help with disposal of SUBOXONE sublingual tablet, call 1-877-782-6966.

General information about the safe and effective use of SUBOXONE sublingual tablet.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take SUBOXONE sublingual tablet for a condition for which it was not prescribed. Do not give SUBOXONE sublingual tablet to other people, even if they have the same symptoms you have. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about SUBOXONE sublingual tablet. If you would

like more information, talk to your doctor or pharmacist. You can ask your doctor or pharmacist for information that is written for health professionals.

For more information, call 1-877-782-6966.

What are the ingredients in SUBOXONE sublingual tablet?

Active ingredients: buprenorphine and naloxone.

Inactive ingredients: polyethylene oxide, hydroxypropyl methylcellulose, maltitol, acesulfame potassium, lime flavor, citric acid, sodium citrate, FD&C yellow #6, and white ink.

Manufactured for Indivior Inc., North Chesterfield, VA 23235 by: Reckitt Benckiser Healthcare (UK) Ltd., Hull, UK, HU8 7DS

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For more information, go to www.SUBOXONE.com or call 1-877-782-6966.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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